

Written Testimony of

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Introduction

Chairman Whitfield, Ranking Member Stupak, and distinguished Members of the Subcommittee, on behalf of Administrator Karen P. Tandy, and the men and women of the Drug Enforcement Administration, thank you for the opportunity to discuss our efforts to combat the illegal distribution of controlled substance pharmaceuticals via the Internet.

The illegal sale of pharmaceuticals over the Internet, the most dangerous of which are also controlled substances, continues to be a significant challenge facing the DEA. Internet-based drug traffickers, most commonly selling pharmaceutical substances or those marketed as pharmaceutical substances, often mask their activities as those of legitimate online pharmacies. Their illicit products have no guarantee of safety or effectiveness and offer no assurance of meeting appropriate handling, storage, or shipping standards. Perhaps most disturbing is that many of these Internet pharmaceutical sites—calling them “pharmacies” gives them more credit than they deserve-- are hiding behind a façade of legitimacy by pretending to ask customers health questions. After customers fill out a superficial questionnaire, which is given an even more cursory review (if any) by a doctor employed by the internet pharmacy, these sites provide pharmaceutical products with no face-to-face medical examination, no tests, no drug interaction screening, and no follow-up care.

Trends in Abuse

A quick search on the Internet reveals thousands of sites offering pharmaceutical controlled substances for sale. The sale of these substances over the Internet is only one way that users illegally acquire pharmaceuticals. The DEA has also investigated cases where prescriptions have been forged; pharmacies have been robbed; unscrupulous

doctors have operated “pill mills” that essentially sell prescriptions or drugs after perfunctory or non-existent medical examinations; or pharmaceuticals have been smuggled into the United States. However they are acquired, the illegal use of pharmaceuticals is one of the fastest growing forms of drug abuse.

- According to SAMSHA’s (Substance Abuse and Mental Health Services Administration) 2004 National Survey on Drug Use and Health, 6.0 million Americans that year reported non-medical use of psychotherapeutic drugs¹.
- The 2003 Monitoring the Future study found that the annual prevalence of Vicodin (Hydrocodone) abuse, a narcotic pain-reliever, by 12th graders was second only to marijuana.
- A 2005 study by the National Center on Addiction and Substance Abuse (CASA) at Columbia University indicated the abuse of pharmaceutical controlled substances grew at a rate of twice that of marijuana, five times that of cocaine, and 60 times that of heroin between 1992 and 2003.
- The Partnership for a Drug-Free America’s 2004 Partnership Attitude Tracking Study found teen abuse of prescription and over-the-counter medications is higher or on par with teen abuse of a variety of illicit drugs—i.e., cocaine/crack (9 percent), Ecstasy (9 percent), methamphetamine (8 percent), LSD (6 percent), ketamine (5 percent), heroin (4 percent), and GHB (4 percent).

Problem of Internet Drug Trafficking

Internet drug traffickers offer drugs for sale without a prescription, without benefit of a legitimate doctor-patient relationship, and at highly inflated prices. Recent DEA investigations involving pharmaceutical drug traffickers using the façade of legitimate online pharmacies reveal pharmaceutical controlled substances being sold at four to ten times the price offered by legitimate “brick and mortar” pharmacies. In all cases, the online scheme is perpetrated by collaborators seeking to profit by trafficking either diverted or counterfeit drugs.

Purchasing pharmaceuticals over the Internet exposes consumers to risks such as purchasing a product that is counterfeit, is improperly handled or stored, is contaminated, or is lacking any warnings or instructions for use. With few exceptions, the consumer has no idea of the content of the substances they are receiving.

Internet traffickers who illegally offer pharmaceutical controlled substances through their websites frequently share characteristics, such as:

- Advertise that no prescription is necessary

¹ Non-medicinal use of prescription-type pain relievers, tranquilizers, stimulants, or sedatives; does not include over-the-counter drugs.

- Fail to participate in any insurance plan and require payment by credit card or cash C.O.D.
- Offer a limited selection of medications for sale, mostly controlled substances and “lifestyle drugs”
- Fail to request the name, address, and phone number of a current physician
- Are willing to deliver drugs to a post office box or other location to avoid detection by authorities
- Deceptively and inaccurately advise about the law and why it is permissible to obtain pharmaceutical controlled substances from foreign countries via the Internet

As part of the scheme, online “consultations” consisting of medical questionnaires filled out by an individual purport, yet fail, to create a legitimate doctor-patient relationship. A legitimate doctor-patient relationship includes a face-to face consultation, where a licensed physician can examine the physical symptoms reported by a patient before making a diagnosis and authorizing the purchase of a prescription medicine. Filling out a questionnaire, no matter how detailed, is no substitute for this relationship.

DEA’s contention that no legitimate doctor-patient relationship exists during these transactions is shared by the medical profession. The Federation of State Medical Boards’ (FSMB) policy on Internet prescribing affirms that the prescribing of medications by physicians based on an online medical questionnaire clearly fails to establish an acceptable standard of medical care.² The American Medical Association (AMA) has stated that a face-to-face evaluation is necessary to diagnose and confirm a medical need for prescribing.³ Further, the AMA declares it unethical for a physician to authorize a prescription for someone identified only through electronic means.

Pharmaceuticals can be purchased legitimately over the Internet, but only if the proper protocols are followed. Currently, there are only 12 DEA-registered pharmacies that have been included on a list of Verified Internet Pharmacy Practice Sites (VIPPS) compiled by the National Association of Boards of Pharmacy (NABP), an independent, non-profit organization of licensing boards. The NABP list identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection. Most other Internet pharmaceutical sales in the United States are legally suspect and potentially very dangerous.

DEA Enforcement Activity

The DEA focuses a significant amount of its resources on attacking Priority Target Organizations (PTOs), which are major drug supply and money laundering organizations operating at the international, national, regional, and local levels that have a significant impact on drug availability. DEA’s core competency, the disruption and dismantlement of drug trafficking organizations impacting the United States, is an

² 2002 – Model Guidelines for the Appropriate Use of the Internet in Medical Practice

³ H120.949 Guidance for Physicians on Internet Prescribing

integral component to both the *Department of Justice's Strategic Plan for Fiscal Years 2003 – 2008* and *The President's National Drug Control Strategy, February 2005*. A concerted organizational attack is the focus of our effort to counter drug traffickers utilizing the Internet to facilitate their illicit trade.

As of October 2005, DEA has initiated 236 investigations of online sales of controlled substances without a prescription. In FY 2004, as a result of online pharmacy investigations, DEA seized over \$14.5 million in cash, bank accounts, property and computers—a 480 percent increase over 2003 (\$2.5 million). Two operations in particular warrant specific mention:

Operation Cyber Chase

- On April 19th and 20th, 2005, the DEA dismantled an international pharmaceutical controlled substance trafficking organization that supplied an estimated 100,000 “customers.” As a result of this Organized Crime Drug Enforcement Task Forces (OCDETF) investigation, the leader of the organization (Akhil Bansal) and 25 co-conspirators were arrested in 4 countries. Their web of operations, however, touched many, many more.

We know that, since at least July 2003, the Bansal organization was responsible for the illegal distribution of 2.5 million dosage units of controlled substances per month to more than 100,000 “customers” without a medical evaluation by a physician. Bansal, an Indian national, supplied eight separate drug organizations that together operated over 200 websites with pharmaceutical controlled substances he arranged to be smuggled from India.

The success of this operation required the cooperation of numerous international, federal, state, and local law enforcement agencies. Participants included the Federal Bureau of Investigation; Immigration and Customs Enforcement; Food and Drug Administration; Postal Inspection Service; and the Internal Revenue Service, as well as several overseas police agencies including the Australian Federal Police; the Narcotics Control Bureau of India; the Costa Rican Judicial Police and two additional Costa Rican federal agencies, The Drug Control Police, and Drug Institute.

State and local law enforcement agencies were integral as well. Officers from Pennsylvania, New York, and Florida, contributed to the success of this operation that resulted in the seizure of over 10 million dosage units of pharmaceutical controlled substances, as well as 231 pounds of Ketamine, and \$8.5 million.

Operation CYBERx

- On September 21, 2005, a 15-month OCDETF multi-agency Internet investigation concluded with the dismantlement of the Johar Saran drug trafficking organization based in Ft. Worth, Texas. The investigation resulted in 19 arrests including the leader of the organization, Johar Saran. This operation is the domestic bookend to Operation Cyber Chase.

Saran and his co-conspirators were arrested for supplying pharmaceutical controlled substances directly to U.S. Internet customers without a medical examination by a physician. We believe that since August 2004, the Saran organization was responsible for the illegal distribution of 3.5 million dosage units of Schedule III-V controlled substances per month.

To date, this investigation has resulted in the seizure of \$16.8 million in assets—\$1 million in U.S. currency, \$5.5 million in bank accounts, \$8.6 million in real property, and \$1.7 million in jewelry. Immediate suspension orders against the DEA registrations of 21 pharmacies and 20 physicians were served in Texas, New York, Florida, Utah, Washington State, and Puerto Rico.

Again, the success of this operation depended upon the cooperation of several other law enforcement agencies. The Federal Bureau of Investigation, the Internal Revenue Service, the Food and Drug Administration, the Texas Department of Health Services, the Texas Board of Pharmacy, and the Florida Department of Law Enforcement were all key to shutting this organization down.

Interagency Collaboration

I highlighted the cooperation between the DEA and our international, federal, state, and local law enforcement partners because, particularly when we are discussing Internet investigations, no significant investigation could take place without a well coordinated effort. Traditional geographic lines of jurisdiction do not exist on the Internet, yet law enforcement must abide by such limits. This means that collaboration is a key component to successfully investigating and arresting those who are nothing more than drug dealers utilizing the anonymity of the Internet to ply their trade.

To better facilitate this interagency cooperation, a federal interagency task force was established in early 2004 with the purpose addressing Internet diversion of drugs and conducting public outreach on pharmaceutical issues in general. Among other groups, DEA, ONDCP, ICE, CBP, and FDA have been represented at task force meetings past and present. A major focus of this evolving task force has been to reach out to business leaders in key industry sectors that provide services used by Internet pharmaceutical trafficking groups. The purpose of this outreach has been twofold: to raise awareness of the problem; and to elicit voluntary efforts to restrict their services from being used by illicit Internet pharmaceutical traffickers. The task force has also provided support to DEA through ICE and CBP special authorities. ICE and CBP have primary jurisdiction

in the enforcement of trans-border smuggling laws and periodically conduct interdiction operations at international mail facilities to identify packages containing illicit pharmaceuticals. The task force meets quarterly and is currently evaluating options for establishing a single reporting point for businesses to report suspicious Internet pharmaceutical sites.

In January and July 2005, DEA in conjunction with the Department of Justice Narcotics and Dangerous Drugs Section hosted a training seminar for Assistant United States Attorneys and DEA personnel to share information on prosecution and investigative strategies for targeting pharmaceutical diversion of controlled substances.

DEA/Private Industry Initiatives

To successfully ply their trade, Internet drug traffickers must rely extensively on the commercial services of three principal business sectors: (1) providers of various internet services – including web hosting, domain name registration, and search; (2) express package delivery companies; and (3) financial services companies, including major credit card companies and third party payment service providers. The DEA has reached out to each of these sectors and is working to educate and facilitate their assistance in shutting down Internet drug trafficking operations.

Several interagency meetings have been held with senior managers and legal counsel from leading Internet, express parcel carriers, and financial services companies. These meetings provided an opportunity for government and the private sector to reach a better understanding of relevant federal laws and explore areas of potential cooperation and voluntary industry actions to curb the expanding illicit sale of pharmaceuticals over the Internet.

In addition to our investigative efforts aimed to shut down Illegal drug sales over the Internet, we are working with the state authorities and representatives of the pharmacy and medical communities to disseminate information regarding activities that can legally be conducted via the Internet

DEA Field Offices have also taken action to help with this threat. Diversion Investigators conduct on-site licensing inspections to ensure that the pharmacy is aware of its responsibilities under the law. New pharmacy applicants or those seeking a renewal through on-line procedures are now linked to the April 2001 Federal Registrant Guidance Document regarding “Dispensing and Purchasing Controlled Substances over the Internet.” Titled “Retail Pharmacy Advisory,” this pop up link takes the applicant to the aforementioned Federal Register notice outlining important information for prescribers, pharmacists, and law enforcement alike.

During the CYBERx investigation, the DEA discovered that the main suppliers were legitimate DEA registrants. While we didn’t find any criminal negligence in this case, we did implement the Internet Distributor Initiative to increase the awareness of DEA registrants regarding their obligations and possible role in the illegal distribution of

pharmaceuticals via the Internet. Based on these meetings, the distributors voluntarily reviewed their customer base and apprised DEA of the termination of business with over 100 known or suspected illegitimate Internet drug trafficking organizations. An analysis of these pharmacies' buying patterns from January – September 2005 revealed over 60,000,000 dosage units of controlled substances had been purchased.

We believe that because of this initiative, many illegal Internet pharmaceutical sites are now unable to purchase large quantities of controlled substances for illegal sale domestically. While this is an effective approach to go after some of the domestic sources of illegal pharmaceuticals supplying the Internet, this will not affect foreign sources of pharmaceuticals. The global nature of the Internet adds to this challenge, as many substances which are controlled in the United States are not controlled elsewhere, and therefore offering to sell these substances on line is not illegal per se.

As a consequence of these and other initiatives, DEA is able to effectively monitor both the supply and dispensing sides of the domestic Internet trafficking problem. The communication between the DEA and the distributors continues to increase. An example of increased cooperation is the fact that distributors are notifying DEA of potential targets, unusual purchasing patterns, and queries from the potential illegitimate Internet pharmacies who have been effectively cut off from supplies by this initiative.

Continuing Challenges

Although no special DEA registration is currently required to market controlled substances online, the tangible aspects of manufacturing, distributing, prescribing, and dispensing pharmaceutical controlled substances remain squarely under the jurisdiction of the Controlled Substances Act. Any legitimate transaction over the Internet must be in compliance with these existing laws. Additional clarification of the roles and responsibilities for professionals seeking to use the Internet to meet the needs of clients would not only allow us to more readily identify legitimate online pharmacies and persons operating and promoting them, but it would also assist in gathering information pointing to patterns of abuse. Such clarification would also help us investigate the illegal traffickers hiding behind the façade of an otherwise legitimate practice.

In addition, there exists no statutory definition specifically outlining what constitutes a valid “doctor/patient” relationship. Further, the penalties associated with the illegal sale of Schedule III-V substances are not as significant as may be warranted.

This does not mean however that Internet drug traffickers can operate freely, as demonstrated by Operations CYBERx and Cyber Chase. The DEA will continue to promote public/private sector and international collaborative actions and use our existing authority to investigate and arrest the individuals illegally selling controlled substances. The increasing support that we receive from key sectors of the Internet-related business community is essential to turning the tide in this critical area of drug trafficking and abuse. The DEA is committed to developing this relationship even further.

Conclusion

The Internet is a universe that by its very nature is impossible to fully monitor, regulate, and control. While drug traffickers who exploit the Internet to target America's most vulnerable continue to pose a significant threat to citizens' lives and health across the country, the DEA has learned from experience and refined its methods by which we identify, pursue, and ultimately dismantle these groups.

I appreciate the opportunity to testify here today and look forward to answering any questions the subcommittee may have.